

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

<b>Appl. No.</b>	<b>:</b>	09/672519	<b>Confirmation No.</b>	<b>:</b>	2122
<b>Appellant</b>	<b>:</b>	Bruce W. GIBBS			
<b>Filed</b>	<b>:</b>	09/27/2000			
<b>TC/A.U.</b>	<b>:</b>	3762			
<b>Examiner</b>	<b>:</b>	Patricia BIANCO			
<b>Title</b>	<b>:</b>	Extracorporeal Blood Processing Methods and Apparatus			
<b>Docket No.</b>	<b>:</b>	BC-0256-P02			
<b>Customer No.</b>	<b>:</b>	24994			

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PO Box 1450  
Alexandria, Virginia 22313-1450

**REPLY BRIEF UNDER 37 C.F.R §41.41**

Pursuant to 37 C.F.R §41.41, Appellants submit this Reply Brief to the Board of Patent Appeals and Interferences, in response to the Corrected Examiner's Answer mailed January 10, 2007 which is in reply to Applicant's Appeal Brief dated July 7, 2006.

**(B) Status of the Claims**

Claim 1-6 stands rejected and are the subject of this appeal.

Claims 7-11 have been canceled.

**(C) Grounds of Rejection To Be Reviewed On Appeal**

A) Whether the rejection of claims 1, 5-6 under 35 USC 102(e) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

B) Whether the rejection of claim 2 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

C) Whether the rejection of claims 3 and 4 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) in view of US Patent No. 5,009,654 to Minshall (Minshall) should be reversed.

## (D) Argument

Appellants still respectfully disagree with the Examiner, and submit that the Examiner has inaccurately represented the teachings of the cited references and based the improper 35 U.S.C. 102(e) and 103(a) rejections on those inaccurate representations.

### **A. 102(e) rejection of Appellants claims 1, 5 and 6 based on Keller.**

It is the Examiner's position that the Keller reference teaches a filter preconnected between a red blood cell collection bag and a red blood cell storage bag. Appellants submit this is not the case. As set forth on column 55, line 30, of Keller "IF (emphasis added) such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture CAN BE (emphasis added) connected to a commercially available red cell filter/bag . . . "

Appellants bring to the Examiner's attention the definitions of several commonly-used words to help elucidate their position. As defined in Webster's 3<sup>rd</sup> New International Dictionary, the word "if" has several definitions- including "in the event that: in case" and "so long as: on condition that." The word "can" is defined as "may perhaps: may possibly." The word "pre" as in "pre-connect" is defined as "earlier than: prior to: before" and "in advance: beforehand."

Keller teaches that if (in the event that, so long as) leukoreduction is desired, a filter can (may possibly) be connected. In Keller, it is only the condition in which leukoreduction of the collected red blood cells is desired, that a filter may perhaps (or may not) be connected. If it is desired to leukoreduce the red blood cell/storage solution, and it is determined that a leukoreduction filter will be used, the filter will be connected to the bag containing the red blood cells to be leukoreduced, but it will not be preconnected or interconnected with the disposable as in Appellants claims, since it will not have been connected to the bag containing the red blood cells in advance (or beforehand).

The Examiner's statement that "Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag" is clearly incorrect. By definition, and as set forth above, a preconnected filter is always connected before, earlier than, or prior to the use of the disposable in an apheresis procedure. Rejection of claims 1-6 based upon Keller should be withdrawn.

**B. 103(a) rejection of claim 2 based on Keller.**

Appellants also respectfully disagree that there is motivation in Keller to rearrange the vent bag (element 94) which is connected to the blood return reservoir (element 150) so as to be interconnected to the red blood cell storage bag as claimed in Appellants claim 2.

Appellants admit that the vent bag (94) of Keller and the air bag as claimed in claim 2 perform the same function, which is to collect air removed from the tubing sets. However, they are substantially different in their locations on the tubing sets, and the Examiner's assertion that it would be obvious to rearrange the parts to produce the invention as claimed in claim 2 is incorrect.

Appellants acknowledge that Keller does teach that "as opposed to vent bag tubing assembly 100, additional integral passageways, integrated chambers and tubing loops could be included in cassette assembly 110 to perform the same functions as the vent bag tubing assembly 100." Keller does not teach that additional integral passageways, integrated chambers and tubing loops could be attached to a red blood cell storage bag as the Examiner stated. Such attachment would not be a "mere rearrangement of parts" as the Examiner suggests. Such attachment would make a completely different configuration, which is not the invention as claimed in Appellants claim 2, and is not even suggested in the Keller reference. Therefore, rejection of claim 2 should be withdrawn.

**C. 103(a) rejection of claims 3 and 4 based on Keller in view of Minshall.**

The Examiner's statement that "the motivation to modify the tubing of Keller with the frangible connectors as taught by Minshall is to provide a sterile connector for the tubing" is also incorrect.

The flexible plastic sleeve 30 of Minshall enables each end of tubing 20a and 28a to be connected together in fluid communication. If (as disclosed on column 6, lines 29-37) in an alternative embodiment, frangible connectors are used instead of a flexible plastic sleeve, the frangible connectors are still used to isolate the terminal end portions of the tubes.

The passage in Keller that the Examiner refers to in making her arguments (column 20, lines 9-13) also teaches the connection of two pieces of tubing together in fluid communication. Both the Minshall and Keller references teach the same thing- which is that two pieces of tubing can be connected together. This is not the frangible connector claimed in Appellants claims 3 or 4. The frangible connector of Appellants invention does not connect two pieces of tubing together. When closed, it prevents the flow of fluid through the tubing. When open, it allows passage of red blood cells through the tubing. If both the Keller and Minshall references disclose the same thing (connecting two pieces of tubing together to make a fluid connection) how can there be a motivation to combine them to produce the claimed invention which is completely different? Also, even if the teachings are combined, they would not yield the invention as claimed in claims 3 and 4, which is "a frangible connector in a first (claim 3) or second (claim 4) tubing." The tubing in claims 3 and 4 may not be claimed using the words "a single distinct piece of tubing" but the claim language of "a first tubing" (claim 3) and "a second tubing" (claim 4) meets this description. The 103 (a) rejections of claims 3 and 4 should be withdrawn.

Respectfully submitted,

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Date



Laura B. Arciniegas (Reg No: 47,466)  
Gambro, Inc.  
10810 W. Collins Ave.  
Lakewood, Colorado 80215 U.S.A.  
Tel. (303) 231-4270